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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,341	11/06/2003	Roderick John Scott	11696-067002	8026

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/702,341	SCOTT, RODERICK JOHN	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/1/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-73* is/are pending in the application.

4a) Of the above claim(s) *44,56 and 70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-43,45-55,57-69 and 71-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/058,825.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/5/04, 11/6/03*. 2/25/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 36-73 are pending.

2. Applicant's election without traverse of Group I, claims 37, 39-43, 45-49, 51-55, 57-61, 63-69, and 71-73 in the reply filed on 8/1/2005 is acknowledged.

Claims 44, 56 and 70 are withdrawn from consideration for being drawn to a non-elected invention.

3. Claims 36, 38, 50 and 62 are linking claims and will be examined along with claims 37, 39-43, 45-49, 51-55, 57-61, 63-69, and 71-73 in the present office action.

Information Disclosure Statement

4. The GenBank Accession Numbers listed on the 1449 dated 11/6/2003 were considered but will not be printed on the patent because the citation format does not include the specified information. The Accession Numbers must include a date, (MPEP § 1.98 Content of Information Disclosure Statement).

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 39-42, 46, 48-49, 52-55, 57-61, 65-68, and 71-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite "80% identity to DNA that encodes the Arabidopsis DNA methyltransferase 1 enzyme", "a mean seed weight that is at least 47% greater than the mean seed weight of seeds that develop on said corresponding plant that lacks said nucleic acid", "a mean seed weight that is at least 81% greater than the mean seed weight of seeds that develop on said corresponding plant that lacks said nucleic acid", "homologue of the Arabidopsis DNA methyltransferase 1 enzyme", "nucleic acid sequence is transcribed into a double stranded RNA", and "said promoter is a female germ line promoter". Applicant fails to point to support for the phrases in the instant specification. Upon a cursory search of the specification, support could not be found. Applicants are required to point to support for the above recited phrases or to amend the claims to delete the NEW MATTER.

Written Description

6. Claims 36-43, 45-55, 57-69 and 71-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid sequence effective for reducing levels of general DNA methylation, an antisense sequence having at least 80% identity to DNA that encodes the Arabidopsis DNA methyltransferase 1 (MET1) enzyme, a homologue of Arabidopsis DNA methyltransferase 1, or a sense sequence having at least 80% identity to DNA that encodes the

Arabidopsis DNA methyltransferase 1 enzyme; and methods and transgenic plants comprising said sequence.

Applicant discloses subcloning the MET1 cDNA, which is 4.7kb long, isolated by RT-PCR from an Arabidopsis cDNA library using the MET1F primer of SEQ ID NO:5 and MET1R primer of SEQ ID NO:6, subcloned into a vector comprising the AGL5 or AP3 promoter in antisense orientation (page 30, Example 3) and transformation into Arabidopsis (page 31, Example 4) or into Brassica campestris and Brassica oleraceae (page 33, Example 5).

Applicant's claims are drawn to a genus of sequences that are effective for reducing levels of general DNA methylation or to a genus of sequences drawn to nucleic acid sequences encoding the genus of Arabidopsis DNA methyltransferase 1 enzyme and homologues thereof. The Applicant does not identify essential regions of the genus of sequences that are effective for reducing levels of general DNA methylation or Applicant does not identify essential regions of the Arabidopsis DNA methyltransferase 1 enzyme, nor does Applicant describe any sense or antisense polynucleotide sequence that has at least 80% identity to said Arabidopsis DNA methyltransferase 1 enzyme. Lastly, Applicant does not disclose any nucleic acid sequence encoding any Arabidopsis DNA methyltransferase 1 enzyme nor a correlation between any structure and function.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A

definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants only describe the subcloning of the MET1 cDNA using the MET1F primer of SEQ ID NO:5 and MET1R primer of SEQ ID NO:6. Applicants fail to describe a representative number of polynucleotide sequences that are effective for reducing levels of general DNA methylation, or a representative number of sequences encoding the Arabidopsis methyltransferase 1 enzyme, or those sequences which fall within the scope of the claimed genus of polynucleotides which are at least 80% identical to the Arabidopsis methyltransferase 1 enzyme. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for any nucleic acid sequence effective for reducing levels of general DNA methylation, or the MET1 enzyme, it remains unclear what features identify any nucleic acid sequence effective for reducing levels of general DNA methylation, or the MET1 enzyme. Since the genus nucleic acid sequences effective for reducing levels of general DNA methylation, or sequences encoding the MET1 enzyme have not been described by specific structural features,

the specification fails to provide an adequate written description to support the breath of the claims.

Enablement

7. Claims 36-43, 45-55, 57-69 and 71-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for the production of seeds, comprising the step of permitting self-pollination or cross-pollination of a plant comprising a nucleic acid sequence effective for reducing levels of general DNA methylation, operably linked to a promoter, wherein seeds that develop on said plant have increased mean seed weight compared to the mean seed weight of seeds from a control plant, or wherein said nucleic acid sequence comprises a sense or antisense sequence having at least 80% identity to DNA that encodes the Arabidopsis

DNA methyltransferase 1 enzyme, or wherein said sequence is a homologue of Arabidopsis DNA methyltransferase 1 enzyme, or wherein said promoter is a gynoecium-specific promoter or a female germ line promoter, or wherein said seeds have a mean seed weight that is at least 47% or 81% greater than the mean seed weight from control plants; a transgenic plant comprising said sequence or wherein said plant produces seed that have a mean seed weight that is at least 47% or 81% greater than the mean seed weight from control plants

Applicant discloses subcloning the MET1 cDNA, which is 4.7kb long, isolated by RT-PCR from an Arabidopsis cDNA library using the MET1F primer of SEQ ID NO:5 and MET1R primer of SEQ ID NO:6, subcloned into a vector comprising the AGL5 or AP3 promoter in antisense orientation (page 30, Example 3) and transformation into Arabidopsis (page 31, Example 4) or into Brassica campestris and Brassica oleraceae (page 33, Example 5). The resultant plant exhibited seeds with increased weight and endosperm.

The state-of-the-art teaches transforming plants with a nucleic acid encoding the Arabidopsis methyltransferase operably linked to a promoter in antisense orientation produces unexpected results. Ronemus et al (1996, Science 273 (2 August):654-657; Listed in IDS) disclose an antisense construct comprising a 4.3kb MET1 cDNA from *Arabidopsis* in antisense orientation operably linked to the CaMV 35S promoter transformed into Arabidopsis, to inhibit the endogenous expression of the MET1 gene (page 654, middle column); producing plants exhibiting perturbed development (page 655, paragraph bridging the left and middle columns). Ronemus et al also disclose that the flowers were female sterile and that some flowers were produced in which there was a three fold increase in stamen number and they were sterile and the flowers exhibited incompletely fused carpels lacking stigmas (page 656, left column, bottom of

1st paragraph). Given the disclosure of Ronemus et al that flowers were female sterile, it is unclear how transforming a plant with Applicant's nucleic acid operably linked to a gynoecium-specific promoter will produce any seeds at all, let alone seeds with increased weight. In addition, given the state-of-the-art, it is also unclear how one of skill in the art can produce seeds with increased weight using a method comprising self-pollinated flowers in lieu of the female sterile and male sterile flowers.

The state-of-the-art teaches down-regulating methylating genes produces unpredictable results. Jacobsen et al (2000, Current Biology 10:179-186; Listed in IDS) teach transforming *Arabidopsis* with a nucleic acid encoding the MET1 protein operably linked to a promoter in antisense orientation caused a decrease in methylation by 80%-90%. Jacobsen et al disclose that "Surprisingly, this work showed that the floral development gene *SUPERMAN* was ectopically hypermethylated and silenced" (page 180, left column, 1st full paragraph).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that are 80% identical to DNA that encodes the Arabidopsis DNA methyltransferase 1 enzyme will encode a protein with the same activity as Applicant's Arabidopsis DNA methyltransferase 1 enzyme. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with

either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

Applicant has not disclosed how one skilled in the art would identify and isolate any nucleic acid sequence effective for reducing levels of general DNA methylation. Applicant has also not disclosed how one skilled in the art would identify and isolate any homologue of Arabidopsis DNA methyltransferase 1 enzyme or any nucleic acid sequence that has 80% identity to DNA that encodes the Arabidopsis DNA methyltransferase 1 enzyme. Applicant has not disclosed any nucleic acid encoding any Arabidopsis methyltransferase 1 enzyme.

Using DNA sequences to reduce expression of the endogenous corresponding gene through the mechanism of sense suppression produces unpredictable results. Gutterson (1995, HortScience 30(5):964-966; Listed in IDS) teaches that the chrysanthemum and petunia chalcone sythase (CHS) genes are 70% identical to each other, and that transforming petunia plants with the chrysanthemum CHS gene did not co-suppress the endogenous petunia CHS gene (page 965, left column, second paragraph). Gutterson reports similar data using another petunia gene in the anthocyanin pathway.

Sense and antisense constructs can behave unpredictably when transformed into a heterolgous plant species. Colliver et al (1997, Plant Mol. Biol. 35:509-522) showed that tranformation of bird's foot trefoil with a construct that was antisense to bean chalcone synthase unexpectedly resulted in transformants with *increased* levels of chalcone synthase transcripts (page 519, left column, 2nd paragraph). Montgomery et al (Trends in Genetics, July 1998, 14(7):255-258) teach that not all transgenes can cause co-suppression in plants and that there is

no basis for predicting which transgenes would have this effect (page 257, column 1, last paragraph).

The state-of-the-art teaches that antisense molecules that exhibit less than 100% sequence identity to the target sequence produce unexpected results. Emery et al (2003, Current Biology 13:1768-1774; Listed in IDS) disclose experiments in which a target sequence of a micro-RNA was changed by two base-pairs. The altered base-pairs caused the complementary micro-RNA not to bind to the target sequence, which subsequently led to an increased expression of the target sequence's encoded protein (page 1769, right column, 2nd full paragraph).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using degenerate primers to nucleic acid sequence that encode any protein that might be useful for reducing levels of general DNA methylation, amplifying the respective sequences or by using non-disclosed fragments of any nucleic acid as specified above, as probes or by designing primers or probes to undisclosed regions of the Arabidopsis DNA methyltransferase 1 enzyme, which Applicant has not identified by a specific nucleic acid sequence, and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when transcribed in a plant are able to down-regulate the endogenous DNA methylating enzyme and reduce the amount of methylated DNA and produce seeds with increased weight.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 36-41, 43, 46-49, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Ronemus et al (1996, Science 273 (2 August):654-657; Listed in IDS).

The claims are drawn to a method for the production of seeds, comprising the step of permitting pollination of a plant comprising a nucleic acid sequence effective for reducing levels of general DNA methylation, said nucleic acid sequence operably linked to a promoter, wherein seeds that develop on said plant have increased mean seed weight compared to the mean seed weight of seeds of a control plant, or wherein said pollinated plant is a dicotyledonous plant, or wherein said nucleic acid sequence comprises an antisense sequence having at least 80% identity to DNA that encodes the Arabidopsis DNA methyltransferase 1 enzyme, or a homologue thereof, or wherein said promoter is a female germ line promoter, or wherein pollination occurs with pollen that lacks said nucleic acid sequence, or wherein said seeds have a mean seed weight that is at least 47% or 81% greater than the mean seed weight from control plants, or a transgenic plant comprising said sequence operably linked to a promoter that is a female germ line promoter.

Ronemus et al disclose an antisense construct comprising a 4.3kb MET1 cDNA from *Arabidopsis* in antisense orientation operably linked to the CaMV 35S promoter transformed into Arabidopsis, to inhibit the endogenous expression of the MET1 gene (page 654, middle column). Ronemus et al disclosed the antisense construct resulted in substantial demethylation of DNA (page 655, left column, bottom of 1st paragraph). It would be inherent that the

transgenic plant of Ronemus et al would comprise a promoter that is a female germ line promoter because the 35S promoter is a constitutive promoter and would express in the female germ line. If it is possible to produce seeds having a mean seed weight that is at least 47% or 81% greater than the mean seed weight from control plants using Applicant's method, then it would be inherent that the method and transgenic plant of Ronemus et al also would have a greater seed weight because the method steps of Ronemus et al are the same as Applicant's, and as such, Ronemus et al anticipate the claimed invention. See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-43, 45-55, 57-69 and 71-73 are provisionally rejected under the judicially created doctrine of double patenting over claims 20-21, 62-67, 69, 71-72, 76-78, and 80-82 of

copending Application No. 10/058,825. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims are drawn to a method for the production of seeds, comprising the step of permitting self-pollination or cross-pollination of a plant comprising a nucleic acid sequence effective for reducing levels of general DNA methylation, operably linked to a promoter, wherein seeds that develop on said plant have increased mean seed weight compared to the mean seed weight of seeds from a control plant, or wherein said nucleic acid sequence comprises a sense or antisense sequence having at least 80% identity to DNA that encodes the Arabidopsis DNA methyltransferase 1 (MET1) enzyme, or wherein said sequence is a homologue of Arabidopsis DNA methyltransferase 1 enzyme, or wherein said promoter is a gynoecium-specific promoter or a female germ line promoter, or wherein said seeds have a mean seed weight that is at least 47% or 81% greater than the mean seed weight from control plants; a transgenic plant comprising said sequence or wherein said plant produces seed that have a mean seed weight that is at least 47% or 81% greater than the mean seed weight from control plants.

Claims 20-21, 62-67, 69, 71-72, 76-78, and 80-82 from the '825 application are drawn to a method for the production of modified endosperm, which comprises the step of introducing a nucleic acid molecule into a plant, the nucleic acid molecule comprising one or more regulatory sequences directing expression in female germ line cells and a sequence whose transcription product comprises a partial or full-length Arabidopsis MET1 sequence, wherein the introduced

nucleic acid is effective for down-regulating one or more DNA methylating enzymes present in the plant, whereby the degree of DNA methylation of nucleic acid in the plant is reduced as compared to a control, or wherein the transcription product comprises an antisense nucleic acid, or wherein the introduced nucleic acid is a partial or full-length Z. mays sequence orthologous to the Arabidopsis MET1, or wherein the nucleic acid is a full or partial sense copy of a DNA methylating enzyme already present in the plant, or wherein the plant is a dicotyledonous plant.

Because seeds are produced as a result of pollination, and because endosperm development is a normal process involved in seed development, it would be inherent that the methods of the '825 application includes a pollination step. Therefore, because the starting materials and method steps of the two applications are the same, the claims of the instant application are drawn to the same invention as claimed in the '825 application.

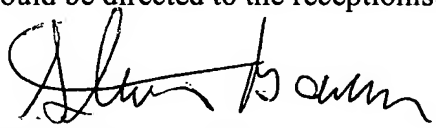
Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
October 12, 2005